Claims

1. A DNA pharmaceutical agent dosage form, having a dense core element coated with a solid reservoir medium containing the DNA pharmaceutical agent.

2. A DNA pharmaceutical agent dosage form as claimed in claim 1, further comprising a stabilising agent that inhibits the degradative effects of free radicals.

3. A DNA pharmaceutical agent dosage form as claimed in claim 2 wherein the stabilising agent is one or both of a metal ion chelator and a free radical scavenger.

4. A DNA pharmaceutical agent dosage form as claimed in claim 3 wherein the metal ion chelating agent is selected from the group consisting of inositol hexaphosphate, tripolyphosphate, succinic and malic acid, ethylenediamine tetraacetic acid (EDTA), tris (hydroxymethyl) amino methane (TRIS), Desferal, diethylenetriaminepentaacetic acid (DTPA) and ethylenediamindihydroxyphenylacetic acid (EDDHA).

5. A DNA pharmaceutical agent dosage form as claimed in claim 3 wherein the non-reducing free radical scavenger is selecting from the group consisting of ethanol, methionine or glutathione.

6. A DNA pharmaceutical agent dosage form as claimed in claim 3 wherein the stabilising agent that inhibits the degradative effects of free radicals, is (a) Phosphate buffered ethanol solution in combination with methionine or EDTA, or (b) Tris buffered EDTA in combination with methionine or ethanol (or combinations of methionine and ethanol).

7. A DNA pharmaceutical agent dosage form as claimed in any one of claims 1 to 6, wherein the solid reservoir medium is an amorphous polyol.

8. A DNA pharmaceutical agent dosage form as claimed in claim 7, wherein the polyol is a stabilising polyol.

9. A DNA pharmaceutical agent dosage form as claimed in any one of claims 1 to 8 wherein the solid biodegradable reservoir medium is a sugar.

10. A DNA pharmaceutical agent dosage form as claimed in claim 9 wherein the sugar is selected from lactose, glucose, sucrose, raffinose or trehalose.

11. A DNA pharmaceutical agent dosage form as claimed in any one of claims 1 to 10 wherein the solid reservoir medium is in the form of a glass.

12. A DNA pharmaceutical agent dosage form as claimed in claim 11, wherein the solid reservoir medium is in the form of a sugar glass.

13. A DNA pharmaceutical agent dosage form as claimed in any one of claims 1 to 12, wherein the DNA is supercoiled plasmid DNA

14. A DNA pharmaceutical agent dosage form as claimed in claim 13, wherein the supercoiled plasmid DNA is stabilised such that after storage at 37°C for 4 weeks greater than 50% of the DNA remains in its supercoiled form.

15. A DNA pharmaceutical agent dosage form as claimed in claim 13, wherein the DNA is stabilised such that when released the ratio of monomer:dimer supercoiled form is within the range of 0.8:1.2.

16. A DNA pharmaceutical agent dosage form as claimed in any one of claims 1 to 15, wherein the pharmaceutical agent is a vaccine.

17. A DNA pharmaceutical agent dosage form as claimed in any one of claims 1 to 16, wherein the solid reservoir medium further comprises a vaccine adjuvant, transfection facilitating agent, DNAase inhibitor or a crystal poisoner.

18. A DNA pharmaceutical agent dosage form as claimed in claim 17, wherein the adjuvant is selected from the group consisting of CpG, a synthetic imidazoquinolines, tucerasol, cytokines, MPL, QS21, QS7 and oil in water emulsions.

19. A DNA pharmaceutical agent dosage form, as claimed in claim 1 wherein the dense core elements are microbeads of a mean particle diameter of between 0.5 to 10 μm.

20. A DNA pharmaceutical agent dosage form as claimed in claim 19, wherein the dense core element is a gold or tungsten microbead.

21. A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 1, comprising making a solution of DNA pharmaceutical agent, reservoir medium, and stabilising agent that inhibits the degradative effects of free radicals in an solvent, followed by coating the at least one dense core element with said solution, and removing the solvent to form a solid reservoir medium containing the pharmaceutical agent and agent that inhibits the degradative effects of free radicals.

22. A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 21, wherein the reservoir medium is a sugar.

23. A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 22 wherein the concentration of sugar prior to drying onto the support member is in the range of 20-40% w/v.

24. A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 23, wherein the solvent is demetalated prior to the process.